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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/813,383	03/20/2001	Kenneth G. Warren	098810/027 8741	3488

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EXAMINER
SNEDDEN, SHERIDAN

ART UNIT	PAPER NUMBER
1653	13

DATE MAILED: 06/17/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/813,383	WARREN ET AL.	
	Examiner	Art Unit	
	Sheridan K Snedden	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE ____ MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 April 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *48-81* is/are pending in the application.

4a) Of the above claim(s) *48-55* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *56-81* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *07 April 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☒ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Response to Amendment

1. This Office Action is in response to Paper #10, filed 7 April 2003. Claims 56-81 have been canceled. Applicant's addition of new claims 56-81 is acknowledged. Claims 56-81 are under examination.

Withdrawal of Objections and Rejections

2. The objections and/or rejections not explicitly restated or stated below are withdrawn.

Objection to Specification

3. The amendment filed 7 April 2003 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: The amendments to SEQ ID NO: 1 in the specification and in the sequence listing add new amino acids 1-60 and 107-170 that were not disclosed in the specification as filed. Support for the additional amino acids is not found in the specification as filed. Applicant is required to cancel the new matter in the reply to this Office Action.

Double Patenting

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686

F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 56-81 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-9 of U.S. Patent No. 5,817,629. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the instant application are within the scope of the claims 1-9 of U.S. Patent No. 5,817,629. Claim 2 of 5,817,629 is directed to a method treating multiple sclerosis (MS) by administration of amino acid residues 84-93 of myelin basic protein (MBP). The recitation of a MS by administration of peptide of at least 8 amino acid contained within the sequences of 61-106 of myelin basic protein (MBP) in claim 56 of the instant application is obvious and within the scope of the patented claim. Additionally, claim 2 of 5,817,629 anticipates claims 57-62 of the instant application as amino acids 84-93 of MBP address the limitation of each of these claims. As claim 1 of 5,817,629 recites that the R1 group may be a peptide, this claim anticipates the claims 63 of the instant application. Claim 1 of 5,817,629 specially recites an

admixture with a pharmaceutical carrier and thus anticipates claim 64. Claim 8 recites the method of administration intraveneously as a single or sequential dose and thus anticipates claims 65-66 of the instant application. Claim 1 of 5,817,629 recites the method of treating MS which from the teachings of the patent would include chronic progressive MS or MS relapse as recited in claims 67-68 of the instant application.

With respect to claims 69-81 of the instant application, these claims recite a method of reducing free anti-MBP in a patient, but are otherwise identical to claims 56-68 of the instant application. As these claims are merely directed toward the mechanism of action in which the peptides act to treat MS, the mechanism is inherent to the treatment process. Thus, it is deemed that claims 69-81 are unpatentable over claims 1-9 of 5,817,629 for the reasons stated above.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 56-81 rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicant is also referred to the Guidelines on Written Description published at FR 66(4) 1099-1111 (January 5, 2001) (also available at www.uspto.gov). The following passage is particularly relevant.

> The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant identifying characteristics, i.e. structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between structure and function structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus. A "representative number of species" means that the species which are adequately described are representative of the entire genus. Thus, when there is substantial variation within a genus, one must describe a sufficient number of species to reflect the variation within the genus. What constitutes a "representative number" is an inverse function of the skill and knowledge in the art. Satisfactory disclosure of a "representative number" depends on whether one of skill in the art would recognize that applicant was in possession of the necessary common attributes or features of the elements possessed by the members of the genus in view of the species disclosed. In an unpredictable art, adequate written description of a genus which embraces widely variant species cannot be achieved by disclosing only one species within the genus.

Claims 56-81 are directed to additions, deletions and substitution of a peptide having the sequence contained in SEQ ID NO: 1. With the exception of the peptides of having a sequence contained in the sequence of SEQ ID NO: 1, the skilled artisan cannot envision the detailed chemical structure of the encompassed polypeptides that would result from additions, deletions and /or substitutions. What amino acids are added, deleted and/or substituted?

Therefore, only isolated peptides comprising a sequence contained within the sequence of SEQ ID NO: 1, but not the full breadth of the claim, meets the written description provision of 35 U.S.C. §112, first paragraph. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

7. Claims 56-81 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The amendments to SEQ ID NO: 1 in the specification and in the sequence listing add

new amino acids 1-60 and 107-170 that were not disclosed in the specification as filed. Support for the additional amino acids is not found in the specification as filed. Only the amino acids of 1-46, currently 61-106, are supported by the specification and claims.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 56-81 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hafler *et al.* (US Patent No 5,571,500) in view of Martin *et al.* (J Immunol. 1990 Jul 15;145(2):540-8) or Ota *et al.* (Nature. 1990 Jul 12;346(6280):183-7).

Hafler *et al.* teach the method of administration of autoantigens for the treatment of autoimmune diseases. Specifically, Hafler *et al.* teach the administration of MBP or fragments thereof for the treatment of MS (see column 6, line 60; claims 1, 3, 6, and 12), and specifically those fragments that are autoimmune responsive (see claim 1; regarding claims 56-63 and 69-76). Hafler *et al.* references teachings in which autoimmune diseases, such as MS, are treated by intravenous injection of MBP (column 2, line18; regarding claims 65 and 78 of the instant application). Hafler *et al.* teaches the pharmaceutical preparation containing a mixture of autoimmune suppressive agents (regarding claims 64 and 77 of the instant application). It is inherent that administration of the pharmaceutical would follow a protocol calling for single or sequential dosing (regarding claims 66 and 79 of the instant application). Treatment of MS, as

taught by Hafler *et al.*, would contain the treatment of a patient with chronic progressive MS and a patient who has had an acute MS relapse (regarding claims 67-68 and 80-81 of the instant application). Claims 69-8135-47 of the instant application as these claims recite a method of reducing free anti-MBP in a patient, but are otherwise identical to claims 56-68 of the instant application. As these claims are merely directed toward the mechanism of action in which the peptides act to treat MS, the scope of the method claims 69-81 in the instant application are taught by Hafler *et al.*.

Hafler *et al.* do not teach peptides of at least 8 to 25 amino acids contained within SEQ ID NO: 1.

Martin *et al.* teach Myelin basic protein (MBP) as a candidate antigen for the autoimmune process important for the pathogenesis of multiple sclerosis (MS). Additionally, Martin *et al.* teach the peptide sequences corresponding to 61-72, 85-95 (particularly relevant for claims 57-59, 62, 70-72, 75), 25-96, 87-95 (particularly relevant for claims 60 and 73), 90-99, 91-98, 91-99, 91-102 (particularly relevant for claims 61 and 74), 97-102, 99-106, and 87-106 of SEQ ID NO: 1 (see Table 1 of Martin *et al.*). Martin *et al.* do not teach the method of administration of the above peptides for the treatment of MS or a pharmaceutical composition containing the peptides.

Ota *et al.* teach the MBP peptides from amino acid residues corresponding to 61-82, 71-92 and 84-102 of SEQ ID NO: 1 (see figure 1) and the involvement of these peptides in MS. Ota *et al.* do not teach the method of administration of the above peptides for the treatment of MS or a pharmaceutical composition containing the peptides.

It would have been obvious to the person of ordinary skill in the art at the time the invention was made to substitute the fragments of MBP in the method of treating MS taught by Hafler *et al.* with the characterized immune reactive fragments of MBP taught by Martin *et al.* and Ota *et al.*. One of ordinary skill in the art would have been motivated to, and expected success by making such a substitution because the peptides taught by Martin *et al.* and Ota *et al.* are know to contain the immune reactivity property found in the whole MBP taught by Hafler *et al.*. Thus, the claimed invention was within the ordinary skill in the art to make and use at the time it was made and was as a whole, *prima facie* obvious.

Conclusion

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheridan K Snedden whose telephone number is (703) 305-4843. The examiner can normally be reached on Monday - Friday, 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (703) 308-2923. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 746-3975 for regular communications and (703) 746-3975 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

SKS
June 16, 2003

SKS

CHRISTOPHER S. F. LOW
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